Novel Multiplex Immunoassay for Simultaneous Detection of Treponemal and Non-treponemal Antibodies in Patients with Syphilis Infection

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Introduction
Syphilis continues to be a global health issue with increasing prevalence in certain at risk populations. Serological tests in combination with clinical presentation remain the primary method for diagnosis and management of syphilis infection worldwide. Screening algorithms may vary from country to country, however, serological tests can be divided into two general categories: Non-treponemal and treponemal tests. Non-treponemal tests such as RPR or VDRL detect antibodies to non-treponemal lipoidal antigens released as a result of cell destruction during infection. Treponemal tests detect specific antibodies generated against the T. pallidum bacterium. Both treponemal and non-treponemal assays are used in the diagnosis of a syphilis infection. This study demonstrates the performance of the BioPlex 2200 Syphilis Total & RPR assay; a novel dual treponemal/non-treponemal syphilis assay that simultaneously detects and differentiates treponemal and non-treponemal antibodies in patients with syphilis infection on the fully automated BioPlex 2200 system.

Methods
Assay Protocol
The BioPlex 2200 Syphilis Total & RPR assay combines an aliquot of patient sample, sample diluent, and bead reagent into a reaction vessel. After the incubation and wash, the bound antibodies are identified using anti-human IgG and anti-human IgM antibody conjugated to phycoerythrin (PE). The identity of each assay is determined by the fluorescence signature of the dyed beads, and the amount of antibody captured by the antigen is determined by the fluorescence intensity of the attached PE. In addition, for every sample processed, two additional internal quality beads, an Internal Standard Bead (ISB) and a Serum Verification Bead (SVB), are present in each reaction mixture to verify detector response and the addition of serum or plasma to the reaction vessel respectively.

Method Comparison
A total of 856 prospective and retrospective samples tested, the BioPlex Syphilis Total assay showed an overall positive and negative agreement of 99.0% and 99.1% respectively against Liaison Syphilis assay. The BioPlex RPR assay showed 95.8% and 98.8% overall positive and negative agreement versus the BD Macro-Vue RPR card test.

Results
The clinical sensitivity of the BioPlex 2200 Syphilis Total & RPR assay was evaluated using a total of 122 samples from patients with known clinical syphilis infection status. Samples were acquired from treated and untreated patients with primary, secondary and latent infection. The BioPlex Syphilis Total assay and the Serodia TPPA assay showed an equivalent overall 93.6% sensitivity for all groups. In contrast, the overall sensitivity of the BioPlex RPR assay was higher at 84% compared to 78.4% for the BD Macro-Vue RPR.

Conclusions
Overall, the BioPlex 2200 Syphilis Total & RPR assay demonstrates excellent clinical performance in comparison to commercially available assays. Incorporating both Syphilis Total and RPR assays onto an automated platform will allow comprehensive syphilis testing that is algorithm independent, reduces labor, increases throughput and improves workflow.

References: